IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
(Case No. 01-489)

In the Application of:	
Haensler *et al.*	
Serial No.: 08/836,576	**Examiner: Z. Lucas**
Filing Date: September 9, 1997	**Group Art Unit: 1648**
For: Adjuvant for Vaccine Composition	**Confirmation No.: 6479**

DECLARATION UNDER 37 C.F.R. § 1.131

Mail Stop Non-Fee Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

We, Jean Haensler, Emmanuelle Trannoy, and Jorge Ronco hereby declare as follows:

1. We are the co-inventors of U.S. Patent Application Serial No. 08/836,576, filed September 9, 1997, entitled, "Adjuvant for Vaccine Composition," which is a 35 U.S.C. § 371 filing of international application PCT/FR95/01495, filed November 14, 1995, claiming the benefit of priority of French application FR 94/13606, filed November 14, 1994.
2. We collaborated on the experimental work described in this Declaration and attached Exhibits, which are true copies of (a) a report describing the invention disclosed and claimed in the present application (Exhibit A) and (b) a letter to Dr. Farrukh Rizvi (Exhibit B), except that all dates have been redacted.
3. The work described in the report of Exhibit A was conducted and completed in France before November 1994.
4. The report in Exhibit A was prepared by Jean Haensler before November 1994 and transmitted before November 1994 to Dr. Farrukh Rizvi in the United States with the letter of Exhibit B.

McDonnell Boehnen Hulbert & Berghoff
300 South Wacker Drive, 32nd Floor
Chicago, IL 60606
(312)913-0001

5. The report of Exhibit A describes the use of the cationic cholesterol derivative, 3 β[N-(N'N'-dimethylaminoethane)-carbamoyl]cholesterol (DC-Chol) as an adjuvant for combination with antigens. As stated in the second full paragraph on page 2 of the report of Exhibit B:

> In the present report we show that particles made of an amphiphile with intrinsic adjuvant and fusogenic properties (e.g., DC-Chol) are particularly suitable for the adjuvantation and delivery of antigenic peptides or proteins in vaccination protocols.

6. Pages 2 and 3 of the report describe

   a. synthesis of DC-Chol,

   b. dispersion of DC-Chol in water with a monovalent flu vaccine (PMsv split vaccine, strain A/Singapore/6/86, No MIA SJ03 µg HA/ml),

   c. administration of the dispersion to BALB/c mice; and

   d. observation of a 40-fold increase in the level of IgG antibodies in response to administration of the combination of DC-Chol and antigen compared to administration of the antigen without DC-Chol.

7. We further declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Sec. 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: _____ _____
Jean Haensler

Date: _____ _____
Emmanuelle Trannoy

Date: _____ _____
Jorge Ronco